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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

REC'D 31 MAR 2004

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Applicant's or agent's file reference P06212PC00/ANH		FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/SE 02/02365	International filing date (day/month/year) 18.12.2002	Priority date (day/month/year) 31.01.2002	
International Patent Classification (IPC) or both national classification and IPC A61F2/06			
Applicant RADI MEDICAL SYSTEMS AB et al.			

- This International preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 4 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

 These annexes consist of a total of 1 sheets.

- This report contains indications relating to the following items:
 - I ☒ Basis of the opinion
 - II ☐ Priority
 - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☐ Certain documents cited
 - VII ☐ Certain defects in the international application
 - VIII ☐ Certain observations on the international application

Date of submission of the demand 15.08.2003	Date of completion of this report 30.03.2004
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Schmierer, U Telephone No. +49 89 2399-2603 

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/SE 02/02365**

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1-9 as published

Claims, Numbers

1-28 as published

29-32 filed with telefax on 17.03.2004

Drawings, Sheets

1/4-4/4 as published

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

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5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-32
	No: Claims	
Inventive step (IS)	Yes: Claims	1-32
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-32
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

- (1) Reference is made to the following document:
D1: US-B1-6287332
- (2) The problem of the present invention is to provide an expandable stent which dissolves or disintegrates inside a blood vessel after a predefined time and a method of manufacturing said stent.
- (3) The closest prior art according to D1 refers to a stent made of zinc having a gold electrode placed thereon.
- (4) The inventive solution is characterised by a stent which has joining portions dissolving faster than the interconnecting portions and a corresponding method of manufacture.
- (5) Said solution is not made obvious by D1, since said document refers to dissolution of the whole stent.
- (6) US-A-2002/0004060 and DE-A-19945049, both cited in the International Search Report, refer to degradation of the stent as a whole rather than disclosing joining portions dissolving faster than interconnecting portions.

29. Expandable stent (1; 3; 7) according to claim 24, **characterized in that** said metal dissolves by corrosion after a pre-defined time inside said body passage.

30. Method for the manufacturing of an expandable metal stent for
5 insertion into a body passage having a mesh structure of interconnecting portions (6) joined together by joining portions (5), said stent, when inserted into said body passage, is adapted to dissolve into smaller parts, wherein the joining portions dissolves faster than the interconnecting portions, the stent comprises a first metal
10 and a second metal, the second metal having an electrochemical potential that differs from the electrochemical potential of the first metal, and wherein said method includes that the metal stent (7) is made from a tube of the first metal, the outer surface and/or the inner surface of the tube being coated with a layer of the second metal.

15 31. Method according to claim 30, further **characterized in that** the tube, which is made of the first metal, is coated with layers of several metals, all of which have different electrochemical potentials.

32. Method according to claims 30 or 31, **characterized in that** said
20 manufacturing involves laser cutting or etching.